REMARKS:

In response to the Office Action mailed November 19, 2009, claims 91-103 and 111-124 have been canceled without prejudice, claims 105 and 106 have been amended, and new claims 125-147 have been added. Accordingly, claims 104-110 and 125-147 are pending with claims 104-110 currently withdrawn from further examination.

The amendments are fully supported by the original disclosure, for example, in the specification, e.g., at page 16, lines 8-18, between page 27, line 29 and page 28, line 6, at page 29, lines 17-30, at page 35, lines 7-24, at page 41, lines 20-29, at page 52, lines 26-30, between page 55, line 20 and page 58, line 4, and between page 60, line 14 and page 67, line 17, and in the drawings, e.g., in FIGS. 7-10, 27, 29, 29A, 31, and 32. No new matter has been introduced.

With respect to the Restriction identified in the Office Action, Applicants have canceled claims 91-103 and 111-124 for consideration in a future divisional application. With respect to claims 104-110, however, Applicants submit that these claims are generic to the species identified in the Office Action since claim 104 does not specify whether the at least one element is substantially bow shaped or planar. This is demonstrated by the addition of new claim 125, which recites that the element of claim 104 is "substantially bow shaped when the appliance is at rest." Applicants would like to point out that the embodiments of FIGS. 7-10 can also have a substantially bow or arcuate shape and therefore also should fall within the elected species.

In the previous Office Action mailed February 3, 2009, the drawings were objected to, and the specification was objected to for informalities. Applicants assume that these objections were properly addressed in Applicants' July 9, 2009 response and that these objections have been withdrawn.

In addition, claims 91-103 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter, and claims 93, 96, 97, 103, and 110 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants assume that these rejections were also properly addressed in Applicants' July 9 response and that these rejections have been withdrawn.

Finally, claims 91, 94, 98, 104, and 107 were rejected 35 U.S.C. § 102(b) as anticipated by German Publication No. DE 1992-114A1 ("the Fege reference"), claims 92, 95, 100, 105, and 109 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference, claims 93, 96, 97, and 106 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference in view of U.S. Publication No. 2003/ 0149445 ("the Knudson et al. reference"), and claims 99, 101-103, and 110 were also rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference in view U.S. Publication No. 2002/ 0189727 ("the Peterson reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the Fege reference, a pair of implants 1 are disclosed that include first ends 48, 54 secured to the spinal column 38 by screws, and second ends 50, 56 disposed against or implanted in the side edges of a tongue 4. As clearly shown in FIG. 1, the implants 1 are embedded directly through tissue between the spinal column 38 and the tongue 4, e.g., including through the masseter muscles 34. The implants 1 are not inserted into the oropharyngeal region, presumably the throat lumen 36 shown in FIG. 1.

Two additional implants 1' are also implanted that extend from the spinal column 38 up at a 45 degree angle up from the implants 1 above the tongue 4 and palate, as clearly shown in FIG. 2. Although the Fege reference makes a general statement that the implants 1 and 1' can become

single and combined with one another, there is absolutely no teaching how such a combined implant could be constructed, nor how such an implant could be introduced through tissue and anchored to the spinal column, as required by the Fege reference.

Turning to the present claims, claim 104 recites a method for treating at least one of sleep apnea and snoring in a human or an animal having an oropharyngeal region with lateral and posterior walls that includes providing an appliance including at least one element having a length extending from a first end to a second end, the appliance comprising a central body portion between end portions adjacent the first and second ends; inserting the appliance into an oropharyngeal region in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region so that the central body portion extends generally laterally across the posterior wall and the end portions support the lateral walls of the oropharyngeal region.

First, as explained in Applicants' July 9, 2009 response, the Fege reference fails to disclose, teach, or suggest an appliance that is inserted into and released in an oropharyngeal region, but instead the Fege implants are implanted ***directly through tissue outside the oropharyngeal region***. Further, the Fege reference does not teach or suggest inserting an appliance into an oropharyngeal region in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region. Accordingly, for these reasons, claim 104 and its dependent claims are also neither anticipated by nor otherwise obvious over the Fege reference.

Turning to claim 127, a method is recited for treating at least one of sleep apnea and snoring that includes introducing an appliance into an oropharyngeal region of a patient, the

appliance comprising a transverse portion between end portions, the transverse portion being substantially bow shaped with the appliance at rest; and securing the appliance within the oropharyngeal region such that the transverse portion extends along a posterior wall and at least partially around opposite lateral walls of the oropharyngeal region and the end portions support the tongue.

First, the Fege reference does not disclose, teach, or suggest securing an appliance that includes a transverse portion between end portions within the oropharyngeal region such that ***the transverse portion extends along a posterior wall and at least partially around opposite lateral walls*** of the oropharyngeal region, as claimed. In contrast, as explained above, the Fege reference merely discloses implants that are implanted directly through tissue and not placed anywhere within an oropharyngeal region.

Second, the Fege reference fails to teach or suggest securing an appliance within the oropharyngeal region such that ***end portions support the tongue***. Although the Fege implants include two ends, one end of each implant is necessarily anchored to the spinal column, and the other end extends through tissue into or above the tongue. Thus, both ends do not support the tongue and the end used to anchor the implant is clearly incapable of supporting the tongue. Accordingly, for these reasons, claim 104 and its dependent claims are neither anticipated by nor otherwise obvious over the Fege reference.

For similar reasons, claims 139 and 147 are also not anticipated by or obvious over the Fege reference. For example, with respect to claim 139, the Fege reference fails to teach or suggest releasing an appliance within the oropharyngeal region so that the ***transverse portion extends generally laterally across the posterior wall and supports the lateral walls*** of the

oropharyngeal region, as explained above. In addition, the Fege reference does not teach or suggest ***inserting an appliance*** into an oropharyngeal region ***in a constrained configuration***, and ***releasing the appliance*** within the oropharyngeal region, as claimed. Instead, the Fege implants are placed surgically such that they extend from the spinal column through tissue into or adjacent the tongue.

Finally, turning to claim 147, the Fege reference fails to disclose, teach, or suggest introducing an appliance into an oropharyngeal region of the patient, and securing the appliance within the oropharyngeal region such that a transverse portion of the appliance extends at least partially around the oropharyngeal region and end portions of the appliance push the tongue forward to hold the airway patent. In contrast, as explained above, one end of each Fege implant is necessarily anchored to the spine and therefore, the ends of the Fege implant are not used to push the tongue forward, nor are they capable of doing so.

The remaining cited references do not provide any additional teaching or suggestion of the features wholly absent from the Fege reference. Therefore, even if the other references could be properly combined with the Fege reference (which Applicants do not concede), the present claims would not be obvious over the cited references.

In particular, the Knudson et al. reference discloses an expander member 20b that is completely incompatible with the Fege implants, particularly, as they disclose mutually exclusive approaches, as explained in Applicants' July 9 response. The Fege reference discloses implants that are implanted into tissue extending from the spinal column to the tongue or above the palate, while the Knudson et al. reference discloses an expander member 20b including spacer bars 26b

that extend across the pharyngeal airway and include wide compression members 24b for contacting the pharyngeal wall.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a one month extension is currently required.

Respectfully submitted,
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